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ALVARO J. LAGUNA

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EXAMINER

MENDEZ, MANUEL A

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Please find below and/or attached an Office communication concerning this application or proceeding.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ALVARO J. LAGUNA and CAREY V. CAMPBELL

Appeal 2009-011003
Application 09/384,900
Technology Center 3700

Before LINDA E. HORNER, JENNIFER D. BAHR, and
STEVEN D.A. McCARTHY, *Administrative Patent Judges*.

McCARTHY, *Administrative Patent Judge*.

DECISION ON APPEAL¹

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the “MAIL DATE” (paper delivery mode) or the “NOTIFICATION DATE” (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

1 The Appellants appeal under 35 U.S.C. § 134 of the Examiner's final
2 decision rejecting claims 24-42. More specifically, the Examiner rejects:
3 claims 24-26 under 35 U.S.C. § 102(b) as being anticipated by
4 Daneshvar (US 5,728,066, issued Mar. 17, 1998);
5 claims 24, 25, 29, 32-34, 37 and 40-42 under § 102(b) as being
6 anticipated by Kraus (US 5,718,680, issued Feb. 17, 1998);
7 claims 28, 30, 31, 36, 38 and 39 under 35 U.S.C. § 103(a) as
8 being unpatentable over Daneshvar and Crocker (US 5,843,116,
9 issued Dec. 1, 1998); and
10 claims 27 and 35 under § 103(a) as being unpatentable over
11 Daneshvar and Ravenscroft (US 5,766,201, issued Jun. 16, 1998).
12 Claims 1-23 are cancelled. We have jurisdiction over the appeal under 35
13 U.S.C. § 6(b).

14 We REVERSE.

15 Claim 24 is the sole independent claim on appeal:

16 24. A sleeve adapted to be mounted on a
17 catheter shaft so as to be formed into an inflatable
18 balloon comprising

19 the sleeve having a first end, a second end,
20 and a middle section;

21 wherein prior to being formed into the
22 balloon by mounting on the catheter shaft at least
23 one of the ends is non-distensible while the middle
24 section of the sleeve is distensible.

1 *Rejections of claims 24-26 under § 102(b) as being anticipated by*
2 *Daneshvar; and of claims 24, 25, 29, 32-34, 37 and 40-42 under § 102(b) as*
3 *being anticipated by Kraus*

4 The analysis of these rejections begins with claim construction. *See*
5 *Medichem, S.A. v. Rolabo, S.L.*, 353 F.3d 928, 933 (Fed. Cir. 2003). Claim
6 24 recites a “sleeve.” The sleeve is “adapted to be mounted on a catheter
7 shaft so as to be formed into an inflatable balloon.” The latter recitation
8 implies that the inflatable balloon into which the sleeve is formed is not the
9 claimed sleeve itself. Furthermore, “prior to being formed into the balloon
10 by mounting on the catheter shaft at least one of the ends [of the sleeve] is
11 non-distensible while the middle section of the sleeve is distensible.” As the
12 Appellants point out, “[i]n order to be perfectly clear that [claim 24 is]
13 defining the sleeve itself and not a completed catheter balloon device, [the
14 Appellants have] included the limitation that these properties exist ‘prior to
15 being formed into the balloon.’” (Reply Br.² 2.) Claim 24 claims a sleeve
16 and not an inflatable balloon or a completed catheter of which the inflatable
17 balloon may be a component.

18 The Appellants correctly contend that “the pending claims do not
19 define a product-by-process[.]” (Reply Br. 1.) A product-by-process claim
20 “is one in which the [claimed] product is defined at least in part in terms of
21 the method or process by which it is made.” *Bonito Boats, Inc. v. Thunder*
22 *Craft Boats, Inc.*, 489 U.S. 141, 158 n. (1989). Although claim 24 recites
23 that the sleeve is adapted to be mounted on a catheter shaft so as to be
24 formed into an inflatable balloon, the claim does not recite any step of a
25 method or process by which the sleeve itself is made. The term “prior to

² The abbreviation “Reply Br.” refers to the Reply Brief filed April 13, 2005.

1 being formed into the balloon by mounting on the catheter shaft” says
2 nothing about any method or process by which the sleeve is made.
3 Therefore, claim 24 is not a product-by-process claim.

4 Any reasonable interpretation of claim 24 is limited to a sleeve
5 “wherein prior to being formed into the balloon by mounting on the catheter
6 shaft at least one of the ends is non-distensible while the middle section of
7 the sleeve is distensible.” The Appellants correctly contend that “each of the
8 references cited by the Examiner describes sleeves that do not have non-
9 distensible ends prior to mounting on a catheter shaft.” (Reply Br. 3.)
10 Daneshvar describes a catheter with an inflatable balloon 4, where the
11 balloon may have fixed ends 5 and 6. (Daneshvar, col. 3, ll. 8-10 and 19-24;
12 fig. 1.) Similarly, Kraus describes a catheter with sheath 22 sealed around
13 an internal tubular member 21 to form an inflatable cavity 23, that is, a
14 balloon. (Kraus, col. 3, ll. 51-53; fig. 2.)

15 The Examiner does not appear to find that either Daneshvar or Kraus
16 discloses a sleeve “wherein prior to being formed into the balloon by
17 mounting on the catheter shaft at least one of the ends is non-distensible
18 while the middle section of the sleeve is distensible.” Instead, the Examiner
19 finds that Daneshvar and Kraus each disclose a “balloon catheter having a
20 sleeve forming a balloon wherein at least one of the ends is non-distensible
21 while the middle section of the sleeve is distensible.” (Ans.³ 5 (internal
22 quotation marks suppressed).) The Examiner’s finding is insufficient to
23 show that either Daneshvar or Krause anticipates the subject matter of claim
24 24 under a reasonable construction of claim 24.

³ The abbreviation “Ans.” and the term “Answer” refer to the Answer mailed February 9, 2005.

Claim 24, when properly construed, claims a sleeve wherein prior to being formed into a balloon by mounting on a catheter shaft, at least one of the ends is non-distensible and not a balloon catheter which may have at least one non-distensible end only after being mounted on the catheter shaft. Neither Daneshvar nor Kraus describes a sleeve wherein prior to being formed into the balloon by mounting on the catheter shaft at least one of the ends is non-distensible while the middle section of the sleeve is distensible. We do not sustain the Examiner's rejection of claims 24-26 under § 102(b) as being anticipated by Daneshvar; or of claims 24, 25, 29, 32-34, 37 and 40-42, under § 102(b) as being anticipated by Kraus.

Rejections of claims 28, 30, 31, 36, 38 and 39 under § 103(a) as being unpatentable over Daneshvar and Crocker; and of claims 27 and 35 under § 103(a) as being patentable over Daneshvar and Ravenscroft

Crocker discloses a catheter 10 including an elongate tubular body 12. (Crocker, col. 3, ll. 56-58.) A distal end 16 of the elongate tubular body 12 is provided with a balloon 18 including an inner balloon 36 and an outer balloon 38. The inner balloon 36 is disposed coaxially within the outer balloon 38. (Crocker, col. 4, ll. 46-48 and col. 5, ll. 20-21.) Substantially nondistensible expansion limiting bands 40, 44 are disposed between the inner and outer balloons 36, 38. (Crocker, col. 5, ll. 21-27.) Figure 3 of Crocker depicts the substantially nondistensible expansion limiting bands 40, 44 as being positioned between the ends of the inner and outer balloons 36, 38 and not at the ends of the balloons. Crocker teaches that the substantially nondistensible expansion limiting bands 40, 44 "may be coated or mounted on the exterior surface of the balloon 18, the interior surface of

1 the balloon 18 or within the wall of the balloon 18.” (Crocker, col. 5, ll. 55-
2 59.)

3 The Examiner finds that, “[i]n figures 2 and 3, Crocker, et al., shows a
4 balloon catheter having a sleeve forming a balloon wherein at least one of
5 the ends is non-distensible (37, 39) while the middle section of the sleeve is
6 distensible (30).” (Ans. 8.)⁴ The Examiner does not appear to find that
7 Crocker discloses a sleeve “wherein prior to being formed into the balloon
8 by mounting on the catheter shaft at least one of the ends is non-distensible
9 while the middle section of the sleeve is distensible.”

⁴ On page 8 of both the Answer and the Supplemental Answer mailed May 19, 2006, the Examiner states that, “[i]n view of these observations, Crocker, et al., anticipates the subject matter in claim 24.” The Appellant calls this statement a new ground of rejection and seeks to distinguish the subject matter of claim 24 from the disclosure of Crocker. (Reply Br. 4.) Several facts indicate that the Examiner did not intend this statement to constitute a separate ground for rejecting claim 24, however. The Examiner’s listing of the Grounds of Rejection on page 3 of both the Answer and the Supplemental Answer does not include a rejection under § 102 of any claim as anticipated by Crocker. The statements on page 8 of both the Answer and the Supplemental Answer, as well as the Examiner’s response on page 9 of the Supplemental Answer, fail to state that claim 24 is rejected as anticipated by Crocker. The Examiner does not provide notice to the Appellant in either the Answer or the Supplemental Answer that a new ground of rejection is being entered. Although a Technical Center Director signed the Supplemental Answer (Supp. Ans. 10), it appears that the Technical Center Director’s signature was intended to approve the filing of a supplemental answer rather than to approve a new ground of rejection (*see* Order Returning Undocketed Appeal to Examiner mailed March 16, 2006). In view of these facts, it appears that the statements on page 8 of both the Answer and the Supplemental Answer were intended to “briefly comment on the teachings of Crocker, et al.” (*see* Ans. 7; Supp. Ans. 7) and not to enter a new ground of rejection against claim 24.

Ravenscroft describes the use of a strip 18 providing resistance via wrapping the strip around an inflatable balloon 28 over a flexible shaft 14 of a catheter 12. The strip facilitates sequential expansion of the inflatable balloon as expansion force is increased. (Ravenscroft, col. 1, l. 67 – col. 2, l. 3 and col. 3, ll. 44-49.) The Examiner does not appear to find that Ravenscroft discloses a sleeve “wherein prior to being formed into the balloon by mounting on the catheter shaft at least one of the ends is non-distensible while the middle section of the sleeve is distensible.”

The Examiner does not articulate persuasive reasoning to explain how the teachings of either Crocker or Ravenscroft might remedy the deficiency in the disclosure of Daneshvar pointed out in connection with the rejection of claim 24. Since the Examiner’s conclusion of obviousness lacks rational underpinning, we do not sustain the Examiner’s rejections under § 103(a) either of claims 28, 30, 31, 36, 38 and 39 as being unpatentable over Daneshvar and Crocker; or of claims 27 and 35 as being unpatentable over Daneshvar and Ravenscroft.

DECISION

We REVERSE the Examiner’s decision rejecting claims 24-42.

REVERSED

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